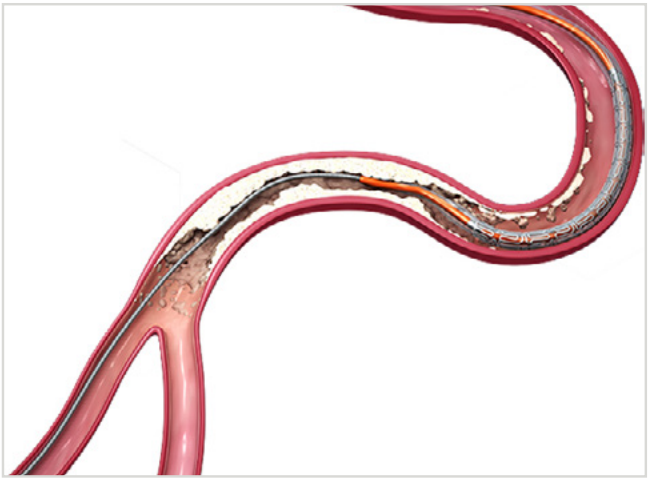
SPIRIT XLV
Post Approval Study

INFORMATION FOR PATIENTS

SPIRIT XLV PAS IS XIENCE SKYPOINT™ LARGE VESSEL (LV) POST APPROVAL STUDY (PAS)

WHAT IS CORONARY ARTERY DISEASE (CAD)?

- Coronary artery disease (CAD) develops when plaque builds up in the vessels and blocks blood flow and oxygen supply to the heart.[1]
- CAD is the most common type of heart disease.[1] About 20.1 million adults aged 20 and older have CAD (~7.2%).[2]
- A common method to open blocked coronary arteries is percutaneous coronary intervention (PCI), also called revascularization.
- Many people with CAD require a stent to keep the coronary arteries open once blood flow has been restored—the Abbott XIENCE™ Stent System is the leading heart stent globally.[3]



HOW DOES CAD AFFECT YOU?[1]

Chest pain or discomfort (angina)

Weakness, light-headedness, nausea

Pain or discomfort in the arms or shoulders

Shortness of breath

1. Centers for Disease Control and Prevention website. Coronary artery disease (CAD). Webpage accessesed on November 2022: https://www.cdc.gov/heartdisease/coronary_ad.htm. 2. Tsao CW, Aday AW, Almarzooq ZI, Beaton AZ, Bittencourt MS, Boehme AK, et al. Heart Disease and Stroke Statistics -2022 Update: A Report From the American Heart Association. *Circulation.* 2022;145(8):e153 -e639. 3. Data on file at Abbott.

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INFORMATION FOR PATIENTS (CONT.)

WHY IS SPIRIT XLV PAS BEING CONDUCTED?

SPIRIT XLV PAS is a Post Approval Study of the XIENCE Skypoint™ Drug Eluting Stent (DES) System manufactured by Abbott. Stents are used for the treatment of coronary artery disease (CAD) and placed in the coronary artery immediately after a balloon angioplasty, supporting and preventing the coronary artery from reclosing.

Abbott has released larger sizes of the XIENCE Skypoint™ Stent System and the SPIRIT XLV Post Approval Study is evaluating the continued safety and effectiveness of the 4.5 mm and 5.0 mm diameters of the XIENCE Skypoint™ Stent System.[4]

WHAT IS INVOLVED IF I CHOOSE TO PARTICIPATE?

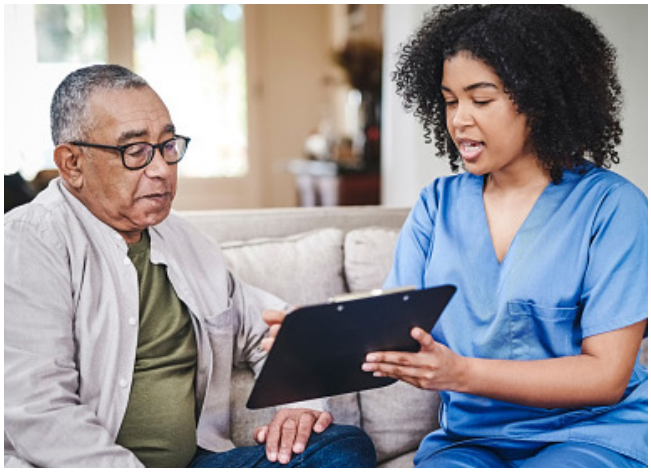
Study participants will have 5 follow-up visits with a dedicated team of specialists focused on their care for a total of 3 years after stent implantation. These visits can be completed in-person or by telephone. Before you are enrolled you will be screened to make sure you are a good candidate for SPIRIT XLV PAS.

WHAT HAPPENS IF I PASS THE SCREENING PROCESS?

Taking part in this research study is entirely voluntary. You will have the procedure to treat your blocked vessel.

You will have 5 study visits over a 3-year period, at the following time points:

- 1 month
- 6 months
- 1 year
- 2 years
- 3 years



NOTE:
You may stop taking part in the research study at any time without penalty or loss of benefits which you are otherwise entitled.

4. ClinicalTrials.gov webpage accessed on 11/07/2022. Trial Identifier: NCT05423379.

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SPIRIT XLV
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LEARN MORE ABOUT SPIRIT XLV PAS
FOR ANY QUESTIONS, PLEASE CONTACT

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Responsible Party – Abbott, Medical Devices
ClinicalTrials.gov ID NCT05423379

FOR MORE INFORMATION, PLEASE REFER TO:

XIENCE Skypoint™ Large Vessel Post Approval Study (NCT05423379)
Full Text View - **ClinicalTrials.gov**

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IMPORTANT SAFETY INFORMATION

℞ ONLY XIENCE SKYPOINT™, XIENCE SIERRA™, XIENCE ALPINE™ (XIENCE™ FAMILY) EVEROLIMUS ELUTING CORONARY STENT SYSTEMS

INDICATIONS

Applies to XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems:

- Indicated for improving coronary artery luminal diameter in patients, including those at high risk for bleeding and those with diabetes mellitus, with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 32 mm) with reference vessel diameters of ≥ 2.25 mm to ≤ 4.25 mm.
- Treating *de novo* chronic total coronary occlusions.

In addition, XIENCE Skypoint™ Stent System is indicated with reference vessel diameters of ≥ 2.25 mm to ≤ 5.25 mm.

CONTRAINDICATIONS

The XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems are contraindicated for use in:

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen.
- Patients with hypersensitivity or contraindication to everolimus or structurally-related compounds, or known hypersensitivity to stent components (cobalt, chromium, nickel, tungsten, methacrylic polymer, fluoropolymer), or with contrast hypersensitivity.

WARNINGS

- **Each stent and the delivery system are for single use only.** Do not reuse, reprocess, or resterilize. Note the product "Use by" date on the package. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and / or delivery system and / or lead to device failure, which may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and / or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device and / or delivery system may lead to injury, illness, or death of the patient.
- It is not recommended to treat patients having a lesion that prevents complete inflation of an angioplasty balloon.
- Antiplatelet therapy should be administered post-procedure.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy
- Judicious selection of patients is necessary, since the use of this device carries the associated risk of stent thrombosis, vascular complications, and/or bleeding events
- The XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems are coated with an everolimus and polymer coating at the full implant stent length. The distal and intermediate portions of the device, the tip, and tapers of the balloon are coated with HYDROCOAT™ Hydrophilic Coating.

Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Implantation of the stent should be performed only by the physicians who have received appropriate training.
- Stent placement should be performed at centers where emergency coronary artery bypass graft surgery (CABG) can be readily performed.
- When the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the SPIRIT family of clinical trials. Compared to use within the specified indications for use, the use of the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems in patients and lesions outside of the labeled indications, including more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.
- The extent of the patient's exposure to drug and polymer is directly related to the number of stents implanted. See Instructions for Use for current data on multiple stent implantation.
- Safety and effectiveness of the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems have not been established for subject populations with the following clinical settings:
  - Patients with prior brachytherapy of the target lesion or the use of brachytherapy for treated site restenosis.
  - Conjunctive use of the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems with either mechanical atherectomy devices or laser angioplasty catheters.
  - Women who are pregnant or lactating, men intending to father children, pediatric.
  - Unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters < 2.25 mm or > 4.25 mm, for XIENCE Skypoint™< 2.25 mm or > 5.25 mm, or lesion lengths > 32 mm, lesions located in saphenous vein grafts, lesions located in unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI < 1) distal to the identified lesions, excessive tortuosity proximal to or within the lesion, recent Acute Myocardial Infarction (AMI) or evidence of thrombus in target vessel, multivessel disease, and in-stent restenosis.
- Formal drug interaction studies have not been performed with the XIENCE Skypoint™, XIENCE Sierra™ or XIENCE Alpine™ Stent Systems because of limited exposure to everolimus eluted from XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems.
  - Everolimus, the active ingredient in the stents, is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
  - Oral everolimus use in renal transplant and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglyceride levels, which in some cases required treatment.
  - Nonclinical testing has demonstrated that the XIENCE Sierra™ and XIENCE Alpine™ Stent Systems in single and in overlapped configurations up to 71 mm, for XIENCE Skypoint™ 91 mm in length, are MR Conditional. See Instructions for Use for detailed scanning conditions.

POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with PCI treatment procedures and the use of a stent in native coronary arteries include, but are not limited to, the following:

- Allergic reaction or hypersensitivity to latex, contrast agent anesthesia, device materials, and drug reactions to everolimus, anticoagulation, or antiplatelet drugs • Vascular access complications which may require transfusion or vessel repair, including: Catheter site reactions, Bleeding, Arteriovenous fistula; pseudoaneurysm, aneurysm, dissection, perforation/ rupture, Embolism, Peripheral nerve injury, Peripheral ischemia • Coronary artery complications which may require additional intervention, including: Total occlusion or abrupt closure, Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection. Perforation/ rupture, Tissue prolapse/plaque shift, Embolism, Coronary or stent thrombosis, Stenosis or restenosis • Pericardial complications which may require additional intervention, including: Cardiac tamponade, Pericardial effusion, Pericarditis. • Cardiac arrhythmias • Cardiac ischemic conditions (including myocardial ischemia, myocardial infarction (including acute), coronary artery spasm, and unstable or stable angina pectoris) • Stroke/ Cerebrovascular Accident (CVA) and Transient Ischemic Attack (TIA) • System organ failures: Cardio-respiratory arrest, Cardiac failure, Cardiopulmonary failure, Renal Insufficiency/failure, Shock • Bleeding • Blood cell disorders • Hypotension and/or hypertension • Infection • Nausea and vomiting • Palpitations • Dizziness • Syncope • Chest Pain • Fever • Pain • Death

The risks described below include the anticipated adverse events relevant for the cardiac population referenced in the contraindications, warnings and precaution sections of the everolimus labels / SmPCs and / or observed at incidences ≥ 10% in clinical trials with oral everolimus for different indications. Please refer to the drug SmPCs and labels for more detailed information and less frequent adverse events.

- Abdominal pain • Anemia • Angioedema • Arterial Thrombotic Events • Bleeding and coagulopathy • Constipation • Cough • Diabetes mellitus • Diarrhea • Dyspnea • Embryo-fetal toxicity • Erythema • Erythroderma • Headache • Hepatic artery thrombosis • Hepatic disorders • Hypersensitivity to everolimus active substance, or to other rapamycin derivates • Hypertension • Infection (bacterial, fungal, viral or protozoan infections, including infections with opportunistic pathogens). Polyoma virus-associated nephropathy (PVAN), JC virus-associated progressive multiple leukoencephalopathy (PML), fatal infections and sepsis have been reported in patients treated with oral everolimus • Kidney arterial and venous thrombosis • Laboratory test alterations• Lymphoma and skin cancer • Male infertility • Menstrual irregularities • Nausea • Nephrotoxicity • Non-infectious pneumonitis • Oral ulcerations • Pain • Pancreatitis • Pericardial effusion • Peripheral edema • Pleural effusion • Pneumonia • Pyrexia • Rash • Renal Failure • Upper respiratory tract infection • Urinary tract infection • Venous thromboembolism • Vomiting • Wound healing complications

There may be other potential adverse events that are unforeseen at this time.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at vascular.eifu.abbott or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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